DrugInsights

Q2 2022

IngenioRx's *DrugInsights* provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, and indications. We continue to closely monitor the FDA landscape to help provide our audiences with an understanding of the current drug and biologic market.

New molecular entities

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Camzyos (mavacamten)	Cardiac myosin inhibitor	First FDA-approved treatment for this indication	Treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms	Recommended starting dose is 5 mg by mouth once a day; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once a day	Bristol Myers Squibb	$89,500 each year

DISCLAIMER: Unless otherwise noted, the information contained in this document was obtained from the Food and Drug Administration (fda.gov) and releases from pharmaceutical manufacturers. Information in this document is accurate as of April 8, 2022.

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC
Carvykti (ciltacabtagene autoleucel)	Chimeric antigen receptor (CAR) T-cell therapy; B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy	Abecma	Treatment of adults with relapsed or refractory multiple myeloma after 4 or more previous lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	Recommended dose is 0.5 to 1 x10^6 CAR-positive viable T cells for each kg of body weight; maximum dose of 1x10^8 CAR-positive viable T cells for each single infusion	Janssen Biotech	$470K each course of treatment
Igalmi (dexmedetomidine)	Alpha-2 adrenoceptor agonist	Adasuve, olanzapine, ziprasidone	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	Can be self-administered under the supervision of a healthcare provider; dose varies from 60 mcg to 180 mcg placed under the tongue; if agitation continues after the initial dose, up to 2 more doses may be given at least 2 hours apart	BioXcel Therapeutics	Not available
Mounjaro (tirzepatide)	Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist	Ozempic, Trulicity, Victoza	Along with diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Starting dose is 2.5 mg injected under the skin once a week • After 4 weeks, increase to 5 mg once a week • If needed, increase in 2.5 mg increments after at least 4 weeks on the current dose • Maximum dose is 15 mg once a week	Eli Lilly	$970 each month

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC
Opdualag (nivolumab/ relatlimab-rmbw)[1]	Combination of a programmed death receptor-1 (PD-1) blocking antibody and a lymphocyte activation gene-3 (LAG-3) blocking antibody	Keytruda, Opdivo, Opdivo plus Yervoy	Treatment of adults and children age 12 years and older with unresectable or metastatic melanoma	Recommended dose for adults and children age 12 years and older who weigh at least 40 kg is 480 mg nivolumab and 160 mg relatlimab administered as 1 intravenous infusion every 4 weeks until disease progression or unacceptable toxicity	Bristol Myers Squibb	$30K each month
Pluvicto (lutetium Lu 177 vipivotide tetraxetan)	Radioligand therapy (RLT)	First targeted radioligand therapy for this use	Treatment of adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy	Administer intravenously at a dose of 7.4 GBq (200 mCi) every 6 weeks. Up to 6 doses	Advanced Accelerator Applications	$255K for 6-dose maximum treatment
Vijoice (alpelisib)	Kinase inhibitor	No other FDA-approved agents for this indication	Treatment of adults and children age 2 years and older with severe signs of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy	Recommended dose for children is 50 mg once a day with food and, for adults, 250 mg once a day with food until disease progression or unacceptable toxicity	Novartis	$32,500 for each 28 days

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC
Vivjoa (oteseconazole)	Azole antifungal	First FDA-approved treatment for this indication	To reduce incidence of recurrent vulvovaginal candidiasis (RVVC) in women with a history of RVVC who are not able to become pregnant	**Vivjoa-only dosage regimen:** •**On day 1:** Administer Vivjoa 600 mg (as a single dose) by mouth and then •**On day 2:** Administer Vivjoa 450 mg (as a single dose), and then •**Beginning on day 14:** Administer Vivjoa 150 mg once a week for 11 weeks **Fluconazole/Vivjoa dosage regimen:** •**On day 1, day 4, and day 7:** Administer fluconazole 150 mg by mouth, and then •**On days 14 through 20:** Administer Vivjoa 150 mg once a day for 7 days, and then •**Beginning on day 28:** Administer Vivjoa 150 mg once a week for 11 weeks	Mycovia Pharmaceuticals	Not available
Vonjo (pacritinib)	Kinase inhibitor with specificity for janus kinase 2 (JAK2), interleukin-1 receptor-associated kinase (IRAK1) and FMS-like tyrosine kinase 3 (FLT3), without inhibiting JAK1	Inrebic, Jakafi	Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 10^9/L	200 mg by mouth twice a day	CTI BioPharma	$19,500 each month

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated WAC
Voquezna Triple Pak (vonoprazan/ amoxicillin/ clarithromycin) Voquezna Dual Pak (vonoprazan/ amoxicillin)	Potassium-competitive acid blocker (PCAB) Amoxicillin (penicillin antibiotic) Clarithromycin (macrolide antibiotic)	Helidac, lansoprazole/ amoxicillin/ clarithromycin, Omeclamox-Pak, Pylera	Treatment of Helicobacter pylori (H. pylori) infection in adults	**Voquezna Triple Pak:** Individuals will take a single vonoprazan 20 mg tablet by mouth, 2 amoxicillin 500 mg capsules, and a single clarithromycin 500 mg tablet twice a day for 14 days **Voquezna Dual Pak:** Individuals will take a vonoprazan 20 mg tablet by mouth twice a day and 2 amoxicillin 500 mg capsules 3 times a day for 14 days	Phathom Pharmaceuticals	Not available
Ztalmy (ganaxolone)	Neuroactive steroid; gamma-aminobutyric acid (GABA) A receptor positive modulator	First approval for this use	Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in individuals age 2 years and older	Take by mouth 3 times a day with dosages based on weight of individual	Marinus Pharmaceuticals	$133K each year

New formulations

Brand (generic)	Description
Adlarity (donepezil)	Donepezil transdermal system approved for the treatment of adults with mild, moderate, and severe dementia of the Alzheimer type.
Aspruzyo Sprinkle (ranolazine)	Ranolazine extended-release oral granules approved for the treatment of chronic angina.
Cuvrior (trientine tetrahydrochloride)	Trientine tetrahydrochloride approved for the treatment of adults with stable Wilson disease who no longer have excess copper in their bodies and can tolerate penicillamine.

New formulations (continued)

Brand (generic)	Description
Ermeza (levothyroxine sodium)	Levothyroxine sodium oral solution approved in adults and children, including newborns, as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Also approved along with surgery and radioiodine therapy in managing thyrotropin-dependent well-differentiated thyroid cancer.
Hyftor (sirolimus)	Sirolimus topical gel approved for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and children age 6 years and older.
Norliqva (amlodipine)	Amlodipine oral solution approved for the treatment of hypertension in adults and children age 6 and older and for the treatment of coronary artery disease and angiographically documented coronary artery disease in individuals without heart failure or an ejection fraction <40%.
Radicava (edaravone)	Edaravone oral suspension approved for the treatment of adults with amyotrophic lateral sclerosis (ALS).
Tlando (testosterone undecanoate)	Oral testosterone approved in adult males for conditions associated with a lack of endogenous testosterone.
Triumeq PD (abacavir/dolutegravir/ lamivudine)	Abacavir/dolutegravir/lamivudine dispersible tablets for oral suspension approved for the treatment of children weighing 10 kg to <25 kg with human immunodeficiency virus type 1 (HIV-1). The original tablet formulation of Triumeq was also expanded to individuals weighing at least 10 kg.
TPOXX (tecovirimat)*	Tecovirimat intravenous (IV) formulation approved for the treatment of smallpox.
Xelstrym (dextroamphetamine)	Dextroamphetamine transdermal system approved for the treatment of attention-deficit/hyperactivity disorder (ADHD) for adults and children age 6 years and older.

* Injectable

New indications

Brand (generic)	Description
Cabenuva (cabotegravir extended-release/rilpivirine extended-release)*	Cabenuva approved for expanded use of every 2-month dosing regimen to include the treatment of human immunodeficiency virus (HIV)-1 infection in adolescents age 12 years and older and weighing at least 35 kg.

Dupixent (dupilumab)*	Dupixent approved to treat eosinophilic esophagitis (EoE) in adults and children age 12 years and older weighing at least 40 kg.

* Injectable

New indications (continued)

Brand (generic)	Description
Edurant (rilpivirine)	Edurant approved for expanded use in combination with Vocabria as an oral, short-term treatment regimen followed by Cabenuva injection dosing regimen for the treatment of human immunodeficiency virus (HIV)-1 virus infection in adolescents age 12 years and older and weighing at least 35 kg.
Enhertu (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for the treatment of adults with unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive breast cancer who have received an anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting and whose disease has recurred during or within 6 months of completing therapy.
Fintepla (fenfluramine)	Fintepla approved for the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in individuals age 2 years and older.
Jardiance (empagliflozin)	Jardiance approved to treat adults with heart failure regardless of left ventricular ejection fraction.
Keytruda (pembrolizumab)*	Keytruda approved as a single agent for individuals with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test, whose disease has progressed after systemic therapy in any setting and who are not candidates for curative surgery or radiation.
Lynparza (olaparib)	Lynparza approved for the adjuvant treatment of adults with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.
Olumiant (baricitinib)	Olumiant approved for the treatment of COVID-19 in hospitalized adults needing supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Opdivo (nivolumab)*	Opdivo approved in combination with platinum-doublet chemotherapy for adults with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting.
Qelbree (viloxazine ER)	Qelbree approved for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults age 18 years and older.
Rinvoq (upadacitinib)	Rinvoq approved for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response or who have not tolerated 1 or more tumor necrosis factor (TNF) blockers.

Rinvoq (upadacitinib)	Rinvoq approved for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or who have not tolerated 1 or more tumor necrosis factor (TNF) blockers.

* Injectable

New indications (continued)

Brand (generic)	Description
Smoflipid (lipid emulsion)*	Smoflipid approval as a source of calories and essential fatty acids for infused nutrition when nutrition by mouth or tube feeding is not possible, insufficient, or not recommended. Expanded to include children.
Ultomiris (ravulizumab-cwvz)*	Ultomiris approved for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.
Veklury (remdesivir)*	Veklury approval expanded to include children age 28 days and older weighing at least 3 kg with positive results of direct SARS-CoV-2 viral testing who are hospitalized or not hospitalized and have mild-to-moderate COVID-19 with high risk for progressing to severe COVID-19, including hospitalization or death.
Vidaza (azacitidine)*	Vidaza approved for children with newly diagnosed juvenile myelomonocytic leukemia.
Vocabria (cabotegravir)	Vocabria approved for expanded use in combination with Edurant as an oral, short-term treatment regimen followed by Cabenuva injection dosing regimen for the treatment of human immunodeficiency virus (HIV)-1 virus infection in adolescents age 12 years and older and weighing at least 35 kg.
Xigduo XR (dapagliflozin/ metformin)	Xigduo XR approved to reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progressing.
Yescarta (axicabtagene ciloleucel)*	Yescarta approved for adults with large B-cell lymphoma (LBCL) that is resistant to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy.
Zerbaxa (ceftolozane/ tazobactam)*	Zerbaxa approved in children from birth to less than age 18 for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis and complicated intra-abdominal infections (cIAI).

* Injectable

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